K131376

elevate ORAL CARE

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5. 510(k) Summary

Submitter:

Company:	Elevate Oral Care
Street:	346 Pike Road, Suite 5
City, State Zip:	West Palm Beach, FL 33411
Country:	USA
Estab. Registration #:	3009603151
Correspondent:	Steve Pardue Managing Member
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Date:	May 10, 2013

AUG 2 7 2013

Name of Device

Proprietary Name:	SmartCoat™ 2.5% NaF Varnish
Classification Name:	Cavity Varnish, Dental 21 CFR 872.3260 as Class II device
Common Name:	Cavity Varnish

Predicate Devices

Device	510(k)
Vanish 5% NaF Varnish	K092141
VivaSens	K030922
Duraphat 5% NaF Varnish	K945794

Description

SmartCoat 2.5% NaF Varnish is classified as a Cavity Varnish (21 CFR 872.3260) because it is a device that provides relief from tooth surface hypersensitivity when applied to dentin surfaces by forming a film that facilitates occlusion of compromised surfaces including open dentinal tubules.

SmartCoat is a topically applied, flavored cavity varnish containing sodium fluoride in a shellac resin based preparation. The varnish is an insoluble viscous liquid that dries once applied to the teeth to form a surface film. The packaging provides an accurate dosing and uniform dispensing mechanism for consistent product mixing and delivery.

Indications for Use

- SmartCoat 2.5% NaF Varnish is intended for use on sensitive teeth, over exposed dentin and root surface sensitivity, and under temporary restorations or cements where post operative sensitivity is of concern.
- Rapid Desensitizer
- Provides rapid relief from sensitive teeth due hypersensitivity

Technological Characteristics

The chemical composition of SmartCoat is similar to the predicate devices and other fluoride varnishes which have been in use for many decades. These products use resins, rosins, modified rosins, hydroxypropyl cellulose, polyurethane, methacrylates, polyethyleneglycol dimethacrylate, and other film forming ingredients to cover dentinal tubules and provide relief from dentinal hypersensitivity.

Shellac resin was chosen as the film forming agent for SmartCoat Varnish due to its extensive safe history in dental and food applications as a film forming barrier and properties similar to existing resins in the Cavity Varnish category. The use of this ingredient rather than colophony rosin eliminates the concern of colophony rosin allergies experienced by some varnishes. Shellac has been used in denture trays and base plates for many years; these trays and plates are currently considered 510(k) exempt (regulation numbers 872.3670, 872.6200).

Many cavity varnishes contain sodium fluoride, calcium phosphates or other mineral ingredients to help occlude tubules. SmartCoat contains sodium fluoride and hydroxyapatite to help occlude tubules.

Summary of Physical Tests

Smart coat was tested using subjective light microscopy analysis at 500x magnification to determine dentin tubule occlusion. Human dentin slabs were prepared as described in the bench performance testing section (Section 18) and varnish was applied to the sample. The varnish was allowed to cure in an incubator and then placed in de-ionized water and stirred vigorously for 6 days. Images were taken immediately after application, and after 3 and 6 days. The specimens were examined for tubule occlusion by image analysis.

All dentinal tubules that were initially covered at time 0 remained covered through the entire treatment period well enough that nearly no dentinal tubules were visible in the coated area. The only visible tubules were still covered by a layer of SmartCoat, however the layer was transparent in a small area near the border. The amount of remaining tubule covering was ranked on a scale of 1-6 with 1 = no occlusion, 2 = 25% or less occlusion, 3 = 25-50% occlusion, 4 = 50-75% occlusion, 5 = more than 75% occlusion, and 6 = complete occlusion. At all measured time points occlusion ratings for SmartCoat Varnish were 6.

It was concluded that SmartCoat varnish will occlude exposed tubules and therefore the varnish should provide relief from tooth hypersensitivity.

Description of Safety and Substantial Equivalence

The chemical components in SmartCoat Varnish have been used in predicate devices, are listed as GRAS ingredients, or both. Shellac and ammonium phosphate have extensive use in food preparation and coatings as well as dental applications that provide significant history of safe use. We believe these facts well support the compatibility of SmartCoat Varnish, and the safety of the applicant device is substantially equivalent to the predicate devices in properties, intended use and composition.

Information provided in this submission confirms the substantial equivalence to the predicate devices with common indications. The data provided in this 510(k) submission also shows that the composition is safe for its intended use based on the biocompatibility assessment and risk assessment conduced according to ISO 10993 and ISO 14971.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 27, 2013

Elevate Oral Care
Mr. Steve Pardue
Managing Member
346 Pike Road, Suite 5
WEST PALM BEACH, FL 33411

Re: K131376
Trade/Device Name: SmartCoat™ 2.5% NaF Varnish
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Codes: LBH
Dated: June 10, 2013
Received: June 11, 2013

Dear Mr. Pardue:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K131376

Device Name: SmartCoat 2.5% NaF Varnish

Indications for Use:

- SmartCoat 2.5% NaF Varnish is intended for use on sensitive teeth, over exposed dentin and root surface sensitivity, and under temporary restorations or cements where post operative sensitivity is of concern.
- Rapid Desensitizer
- Provides rapid relief from sensitive teeth due to hypersensitivity

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
2013.08.27 15:30:24 -04'00'
for M. Susan Runner, DDS, MA

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K131376